

REMARKS

Claims 3-28 are active in the present application.

At present, the primary sterilization process for medical instruments employs an ethylene oxide gas. However, due to problems resulting from residual gas, in recent years a method of sterilization with radiations (γ -rays, electron rays) came into favor. Radiation sterilization also encounters several problems, most prominent of which is a reduction in the adhesion properties of adhesive products comprising an acrylic adhesive after irradiation compared to the adhesion properties. This undesirable result gives rise to adhesion of adhesive tapes, adhesive plasters or surgical drapes comprising an acrylic adhesive becoming lower than predetermined adhesion, or adhesive labels stuck on medical instruments being easily released. (page 1, lines 11-20).

The present invention solves the problems associated with sterilization of medical instruments and adhesives by providing, in part, a method for sterilizing a radiation-resistant medical adhesive product comprising an acrylic polymer, a crosslinking agent, and a radiation-resistant agent selected from the group consisting of rosin, rosin derivatives, terpene resin, terpene phenol resin, aromatic modified terpene resin, hydrogenated terpene resin, aliphatic petroleum resin, aromatic petroleum resin, copolymerized petroleum resin, alicyclic petroleum resin, hydrogenated petroleum resin and alkyl phenol resin, wherein said method comprises sterilizing said radiation-resistant medical adhesive product with radiation wherein said radiation is with either γ -rays or electron rays. (see Claim 8). Applicants submit that the art of record neither discloses, nor suggests such a method. Reconsideration is respectfully requested.

The rejections of Claims 8 and 25-28 under 35 U.S.C. §102(b) over Bernard et al (US 5,130,375) and of Claims 8 and 25-28 under 35 U.S.C. §103(a) over Bernard et al (US 5,130,375), are obviated by amendment.

Bernard et al disclose a tackified pressure-sensitive adhesive comprising an acrylic based pressure-sensitive adhesive polymer and a reactive tackifier (see Abstract; column 1, line 66 to column 2, line 6; and column 6, lines 24-68). The reactive tackifier disclosed by Bernard et al has a pendant vinyl unsaturated organo group (see column 2, lines 7-24) and is preferably prepared from a rosin precursor resin such as abitol, rosin acid, rosin amine, etc. (see column 3, lines 7-10 and column 5, lines 55-57).

At column 7, lines 3-8, Bernard et al explicitly state:

The novel tackifiers of this invention may be added to the formed polymer and grafted through the vinyl group to the polymer chain by irradiation or combined with monomers or prepolymers and interpolymerized with the monomers or prepolymers to become an integral part of the polymer chain.

This disclosure by Bernard et al is in direct contrast with the present invention. Specifically, the radiation-resistant agent used in the present invention does not contain vinyl unsaturated organo groups and corresponds to the rosin precursor resin of Bernard et al, *not* the reactive tackifier (see page 2, line 20 to page 3, line 1).

The radiation-resistant agent used in the present invention does not react with each other nor with an acrylic polymer by means of UV or EB radiation, since the agent does not contain any vinyl unsaturated organo groups. Accordingly, the presently claimed invention requires the presence of a crosslinking agent (see Claim 8 as presently amended).

At no point does Bernard et al disclose or suggest the use of a crosslinking agent. Bernard et al merely disclose abitol, rosin acid, modified rosin esters, etc. as a raw material (rosin precursor resin) of the reactive tackifier.

The standard for determining anticipation requires that the reference “must teach every element of the claim” (MPEP §2131). Therefore, the absence of any disclosure or suggestion in any of the art of record of the crosslinking agent would necessarily make this reference fail to anticipate the present invention.

Moreover, Further MPEP §2142 states: “To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation... to modify the reference... Second, there must be a reasonable expectation of success. Finally, the prior art reference... must teach or suggest all the claim limitations.” Applicants note that in the absence of any suggestion of the crosslinking agent, Bernard et al can not provide any reasonable expectation of success. As such, this reference, on its own, fails to support a *prima facie* case of obviousness.

Applicants further note that although Bernard et al disclose the use of radiation with an electron beam (electron rays; see Abstract and Examples 5 and 6), the purpose of irradiation is anything but sterilization. As is clearly evident from the Abstract and Examples 5 and 6 of Bernard et al, the purpose of the electron beam irradiation is to cure (crosslink) a mixture of their acrylic based pressure-sensitive adhesive polymer and the reactive tackifier (described above). Accordingly, Bernard et al’s silence with respect to sterilization further underscores the novelty of the claimed invention in view of this reference.

In view of the foregoing, Applicants request withdrawal of the rejections over Bernard et al.

The rejection of Claim 24 under 35 U.S.C. §103(a) over Bernard et al (US 5,130,375) in combination with Saito et al (US 5,429,590) is obviated in part by amendment and traversed in part.

Bernard et al is discussed above. And as stated above, Bernard et al fails to disclose or suggest the presence of the crosslinking agent, as well as the irradiation for sterilization. Applicants note that Saito et al fail to compensate for these deficiencies as Saito et al does not disclose or suggest the radiation-resistant agent used in the present invention..

Notably, the Examiner cites Saito et al for the use of electron rays for sterilization purposes. However, Applicants direct the Examiner's attention to Examples 5 and 6 of Bernard et al, which disclose that the irradiation dosage of the electron beam is 20 kGy. At no point is any other dosage disclosed. Saito et al specifically disclose at column 11, lines 65-68: "if the dosage is **25 kGy or higher**, the irradiation also functions as the sterilization defined by the medical treatment-related laws and regulation." (emphasis added)

In view of this disclosure in Saito et al, it is clear that the lower irradiation dosage utilized by Bernard et al is insufficient to function for sterilization as defined by the medical treatment-related laws and regulation. Accordingly, the disclosure by Saito et al further proves the deficiencies in the disclosure of Bernard et al rather than compensates for them.

In view of the foregoing, Applicants request withdrawal of this ground of rejection.

The rejection of Claims 8 and 24-28 under 35 U.S.C. §112, second paragraph, is obviated by amendment.

Applicants wish to thank Examiner Reddick for the helpful suggestions to overcome this ground of rejection. Consistent with this indication, the claims have been so amended.

Withdrawal of this ground of objection is respectfully requested.

Finally, Applicants note that the incorporation by reference statement on page 7 is proper. Applicants agree with the Examiner that it is improper to incorporate by reference

essential material from a foreign application or patent. However, "Essential material" is defined as that which is necessary to (1) describe the claimed invention, (2) provide an enabling disclosure of the claimed invention, or (3) describe the best mode (MPEP §608.01(p)). In the present application, Applicants have not relied upon the disclosure of JP 2000-309665 for written description, enablement, and/or best mode and, therefore, the material referred to therein is "nonessential." As set forth in MPEP §608.01(p), "Nonessential subject matter" may be incorporated by reference to (1) patents or applications published by the United States or foreign countries or regional patent offices, (2) prior filed, commonly owned U.S. applications, or (3) non-patent publications however, hyperlinks and/or other forms of browser executable code cannot be incorporated by reference. Accordingly, no further amendment is necessary and withdrawal of this objection is requested.

Applicants submit that the present application is now in condition for allowance.

Early notification of such action is earnestly solicited.

Respectfully submitted,

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